

Appl. No. 10/803,392
Amdt. Dated 27-Apr-06
Reply to Office Action of March 8, 2006
Attorney Docket No. : 6006-146

Remarks/Arguments

CLAIMS

Claims 1-5 and 7-11 are currently pending in the application. In the Final Office Action of March 8, 2006, the Examiner rejects pending claims 1-5, 7-9, and 11 on various grounds. The Examiner indicates that claim 10 is allowable. Applicants amend claims 1-3, 5, 7-8, and 11 to further clarify the invention. The rejections to claims 1-5, 7-9, and 11 are traversed. Applicants respond to each rejection as subsequently recited herein, and respectfully request reconsideration and further examination of the present application.

A. Applicants traverse the Examiner's rejection of pending claims 2-5 under 35 U.S.C. §112 first paragraph for failing to comply with the written description requirement.

According to the Examiner, the "terminology 'generally uniform in width' is not supported by the original disclosure." (First Paragraph of Page 5 of the Final Office Action.) Applicants respectfully disagree. As well-recognized by the courts, "drawings alone may provide a 'written description' of an invention as required by § 112". *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565; *see also Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1154 (stating that "the written description requirement can be satisfied by words, structures, figures, diagrams, formulas, etc." and relying on an illustrative figure in determining that the requirement was satisfied) (emphasis in original); *see also In re Smythe*, 480 F.2d 1376, 1384 (C.C.P.A. 1973) (stating that the written description test can be satisfied by an inherent disclosure of the invention so long as the inventor's possession of the claimed invention is obvious).

Contrary to the Examiner's assertion, it is abundantly clear to those skilled in the art that Applicants' disclosure as described in the pending application inherently possesses the "struts are ~~generally~~ substantially uniform in width" limitation as is set forth in claim 2. To remove any ambiguity, Applicants refer specifically to Figure 2 and Figure 6 of the pending application.

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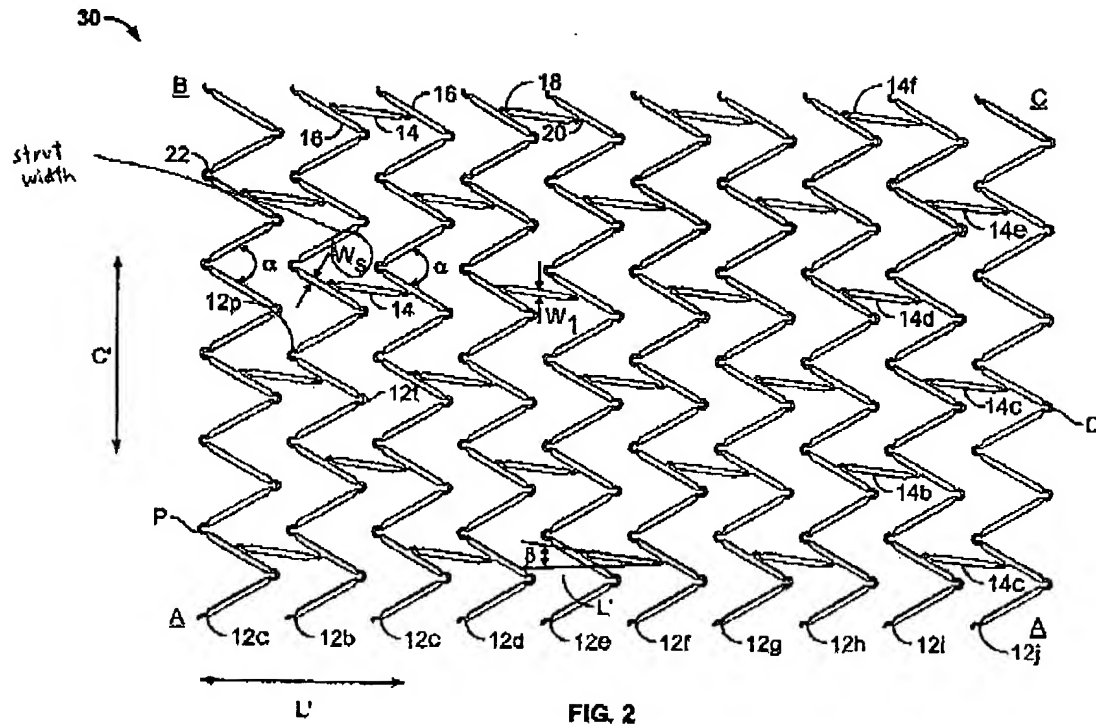


FIG. 2

As clearly shown in Figure 2, Applicants assign the term W_s to describe the strut width. Specific references to the strut width (W_s) can be found in the specification (Page 7, Line 27; Page 8, Lines. 12-13; and Page 14, Line 14). To those skilled in the art, Applicants' assignment of an expression (W_s) to the strut width logically indicates that the strut width as disclosed in the pending application is inherently substantially uniform. Had Applicants' strut width not been substantially uniform, Applicants use of the expression (W_s) would have been a contradiction.

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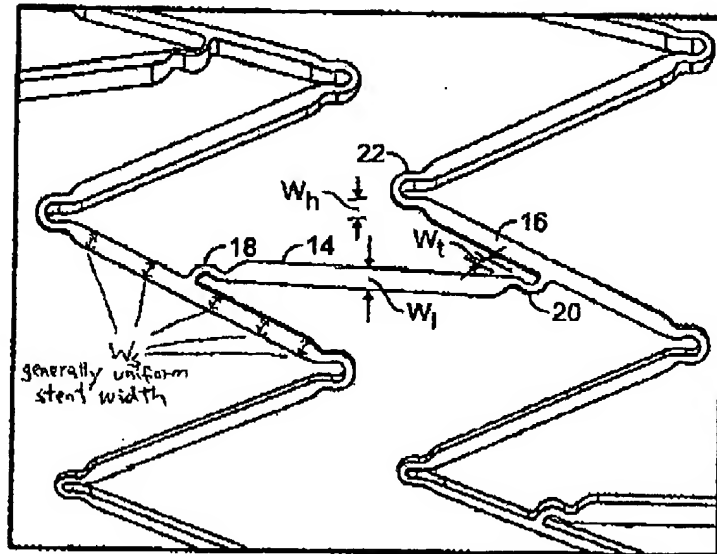


FIG. 6

Figure 6 provides a close up view of Applicants' stent structure. Applicants respectfully remind the Examiner that the standard for the written description requirement is that the patent's "disclosure must allow one skilled in the art 'to visualize or recognize the identity of' the subject matter purportedly described." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002) (quoting *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573 (Fed. Cir. 1997)). From reviewing the drawing, it is abundantly clear to those skilled in the art that Figure 6 (like Figure 2) provides complete and unqualified support for the "struts are substantially uniform in width" limitation as set forth in claim 2.

Accordingly, Applicants respectfully submit that the Examiner's 35 U.S.C. §112 first paragraph rejection is improper and should be withdrawn.

B. Applicants traverse the Examiner's rejection of pending claims 1, 7-9 and 11 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. US 6,730,116 to Wolinsky et al.

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With regard to claims 1 and 11, Applicants respectfully remind the Examiner that for an anticipation rejection to be proper, “[t]he *identical* invention must be shown in the as complete detail as is contained in the ... claim.” (Emphasis added). *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (holding that anticipation requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”). Moreover, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond*, 910 F.2d 831, 832-833 (Fed. Cir. 1990) (stating that anticipation can not be established by mere equivalents).

Contrary to the Examiner’s suggestion, the rings 91 taught by U.S. Patent No. US 6,730,116 to *Wolinsky et al.* (hereinafter referred to as “*Wolinsky*”) do not anticipate Applicants’ struts. Applicants reference the Response filed on January 17, 2006, wherein Applicants show that the struts described in the pending application are *structurally* different from *Wolinsky*’s rings 91. Whereas Applicants’ struts inherently possesses a substantially linear shape, *Wolinsky*’s rings 91 possess a curved shape.

In response to Applicants’ Response, the Examiner suggests that *Wolinsky*’s rings 91 are capable of forming a linear shape when stretched. In accordance with this conclusion, the Examiner modifies a figure from *Wolinsky* to illustrate how the Examiner imagine the ring structure 91 would appear, if it was expanded. Applicants submit that the Examiner’s “what if” recreation of *Wolinsky*’s stent is improper and constitutes unsupported speculation. Without firsthand knowledge of the precise conditions of the rings (composition of ring structure, tensile strength, temperature, pressure, etc.) at hand, the Examiner can not viably conclude that the ring structure 91 of *Wolinsky* would stretch in the manner as imagined and as sketched by the Examiner on the lower right figure of page 4. Applicants submit that the generally linear ring structure 91 as imagined by the Examiner (and as depicted on the lower right figure of page 4) is not possible. Moreover, even assuming *arguendo* that this structure was somehow physically possible under certain conditions, the Examiner’s argument would still be improper. *See Continental*

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Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991) (holding that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.")

Claims 7-9 depend from claim independent claim 1. Therefore, dependent claim 7-9 includes all of the elements and limitations of independent claim 1. It is therefore respectfully submitted by Applicants that dependent claims 7-9 are allowable over *Wolinsky* for at least the same reason as set forth herein with respect to independent claim 1 being allowable over *Wolinsky*. Thus, withdrawal of the rejection of dependent claims 7-9 under §102(e) is respectfully requested.

For the reasons stated above, Applicants submit that the Examiner's anticipation rejection of claims 1, 7-9, and 11 is improper and thus should be withdrawn.

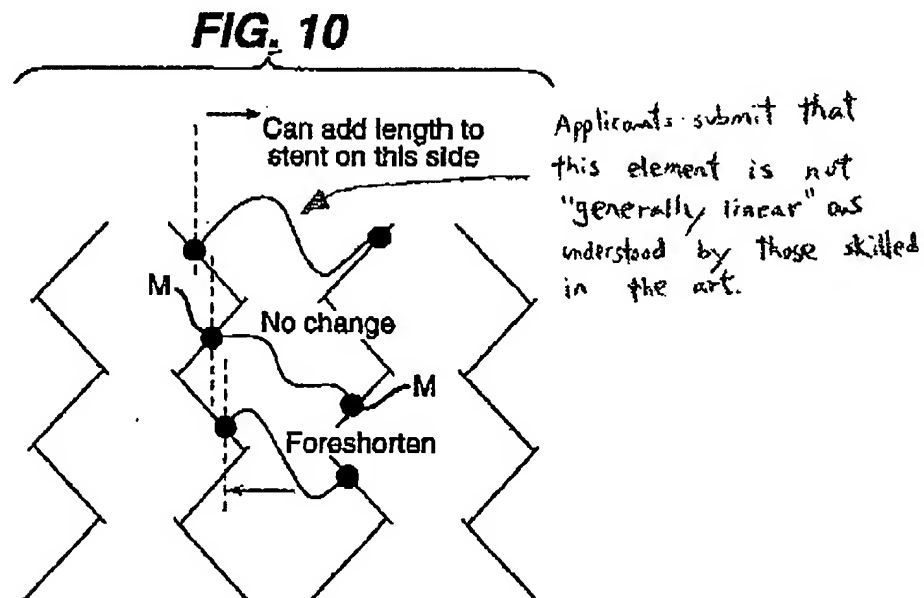
C. Applicants traverse the Examiner's rejection of pending claims 1 and 9 under 35 U.S.C. §102(a) as being anticipated by U.S. Patent Publication No. 20020123798 to *Burgermeister*.

Contrary to the Examiner's inference, there is no indication that Figure 10 of U.S. Patent Publication No. 20020123798 to *Burgermeister* (hereinafter referred to as "*Burgermeister*") represents anything more than a "*schematic[s] of the theory behind expansion of stent.*" (Emphasis added.) (See Paragraph No. 0032). As widely known to those skilled in the art, a schematic drawing generally *does not represent an actual physical depiction* of the subject it portrays. Instead, it is merely a simplified diagram representing a subject. (For instance, as known to those skilled in the art, a schematic drawing of an electrical circuit would not constitute an actual physical representation of the electrical circuit. Instead, it would merely represent a simplified theoretical diagram of the electrical circuit.) Accordingly, the Examiner's reliance on the schematic drawing shown in Figure 10 as being an actual physical depiction of *Burgermeister's* stent is inappropriate.

While Applicants maintain that Figure 10 is not an actual physical representation of *Burgermeister's* stent, even assuming *arguendo* that Figure 10 is a physical

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representation, *Burgermeister* still fails as an anticipation reference because it fails to disclose, teach or suggest “*substantially linear* interconnecting elements interconnecting adjacent pairs of circumferential elements” (emphasis added) as recited in claim 1. The Examiner contends that *Burgermeister* teaches of a generally linear interconnecting element because it teaches of interconnecting elements that are “linear in the center section, generally straight over a length thereof” (Second Paragraph on Page 7 of the Final Office Action). Applicants strongly but respectfully disagree with this characterization. Those of ordinary skill in the art would not interpret or characterize the interconnecting element of *Burgermeister* shown below to be “generally linear” or “substantially linear.”



Applicants respectfully remind the Examiner that claim 1 recites “substantially linear interconnecting elements”, *not* “interconnecting elements that are linear in the center section and generally straight over a length thereof,” as characterized by the Examiner. Accordingly, Applicants submit that the rejection is improper and thus respectfully request that the Examiner withdraw the rejection.

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D. Applicants traverse the Examiner's rejection of pending claims 2-5 under 35 U.S.C. §103(a) as being unpatentable over *Wolinsky* in view of U.S. Patent No. 6,540,774 to *Cox*.

According to the Examiner, "[I]t would have been obvious to one of ordinary skill in the art at the time the invention was made to interconnect the struts at the peaks and valleys by a [sic] hinge elements with a width narrower than a width of the struts as taught by Cox on the stent of Wolinsky et al in order to reducing [sic] stress at the hinge" (First Paragraph on Page 8 of the Final Office Action).

Applicants respectfully disagree with the Examiner's assertion. First of all, as discussed above in Section B of this Response, *Wolinsky* does not teach or suggest all of the limitations of claim 1, and cannot, therefore, by itself, provide the proper basis for rendering obvious any claims depending therefrom. See MPEP 2143.03; see also *In re Royka*, 490 F.2d 981, 985 (holding that all claim limitations must be taught or suggested by the prior art).

Second of all, Applicants submit that modifying *Wolinsky's* stent configuration with the hinge elements taught by Cox would have rendered *Wolinsky's* stent unsatisfactory for its intended use. A close review of Cox reveals that Cox's stent incorporates generally linear struts that functionally correspond to Applicants' struts. (As a side note, Cox does not teach of interconnecting elements that connect to the midpoints of the struts.) Thus, Cox's stent, which incorporates generally linear struts, is vastly different from *Wolinsky's* rings 91. Whereas the inflection points of Cox's struts are located at the ends of the struts, the inflection points of *Wolinsky's* rings 91 are located at a midpoint where two rings connect. (As discussed previously, Applicants disagree with the Examiner's position that two separate halves of two separate rings connected at an inflection point structurally corresponds to a generally linear strut.)

Applicants kindly remind the Examiner that for an obviousness rejection to be proper, the proposed modification cannot render the prior art unsatisfactory for its intended use. See *In re Gordon*, 733 F.2d 900, 901 (Fed. Cir. 1984). In the pending

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matter, because of structural differences between *Wolinsky's* and *Cox's* stent, it would not have been feasible for one of ordinary skill in the art to have provided hinge elements to *Wolinsky's* rings 91. Incorporating *Cox's* hinge elements to *Wolinsky's* rings 91 would have doubled the number of inflection points on *Wolinsky's* struts. Thus, under the Examiner's hypothetical construct, each given ring 91 would have had two inflection points (one on the midpoint and one on the hinge element). Having two inflection points for each ring 91 would inherently have caused problems relating to structural integrity. (As known to those skilled in the art, an object with one hinge and one inflection point generally has more structural integrity and is more stable than one with many hinges and many inflection points.) Compromises to the structural integrity of this hypothetical *Wolinsky-Cox* stent would have weakened the stent, thereby making it more susceptible to an unacceptable collapse. Because the primary purpose of a stent is to open a vessel and increase the vessel's diameter, a collapsed stent is a failed stent. To conclude, Applicants submit that incorporating additional inflection points by adding *Cox's* hinge element, as suggested by the Examiner, would have inherently decreased the effectiveness of *Wolinsky's* original stent by weakening its structural integrity. Accordingly, the Examiner's proposed modification of *Wolinsky's* stent is improper, and Applicants respectfully request that the obviousness rejection of claims 2-5 be withdrawn.

EXAMINER INTERVIEW

Applicants express thanks to the Examiner for his graciousness in taking the time to interview the undersigned on April 17, 2006. During the interview, the undersigned presented the very arguments set forth in this Response. Thereafter, the Examiner proposed that the following amendments would render claims 1-5 and 7-9 patentable over the art of record: (1) removing the term "generally" before the term "linear" in the claims; and (2) adding the limitation, "wherein the hinge elements have a width narrower than a width of the struts."

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Summary

The Examiner's rejections of claims 1-5, 7-9, and 11 have been obviated by the above remarks. Additionally, in view of the Examiner's proposed amendments, Applicants amend claims 1-3, 5, 7-8, and 11 to recite limitations, which should distinguish the invention from the art of record. Accordingly, Applicants submit that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited. If any question remain that may be resolved in a telephone interview, Applicants ask the Examiner to contact the undersigned.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Response is being concurrently filed with an Amendment Transmittal Letter including a fee calculation sheet, any applicable Request for Extension, and fee calculations. The Director is authorized to deduct any additional expenses from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Respectfully submitted,



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